PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 1322-035 PCT	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2005/018631	International filing date (day/month/year) 23 May 2005 (23.05.2005)	Priority date (day/month/year) 21 May 2004 (21.05.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ACCU-BREAK PHARMACEUTICALS, INC.		

1.					
	International Searching Authority under Rule 44 bis.1(a).				
2.	This REPORT consists of a tota	l of 5 sheets, including this co	over sheet.		
	In the attached sheets, any refer to the international preliminary		the International Searching Authority should be read as a reference er I) instead.		
3.	This report contains indications	relating to the following item	s:		
	Box No. I	Basis of the report			
	Box No. II	Priority			
	Box No. III	Non-establishment of opinapplicability	nion with regard to novelty, inventive step and industrial		
	Box No. IV	Lack of unity of invention	ı		
	Box No. V		Article 35(2) with regard to novelty, inventive step or industrial dexplanations supporting such statement		
	Box No. VI	Certain documents cited			
	Box No. VII	Certain defects in the inter	rnational application .		
	Box No. VIII	Certain observations on th	e international application		
4.	4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).				
			Date of issuance of this report 21 November 2006 (21.11.2006)		
	The International Bure	au of WIPO	Authorized officer		
34, chemin des Colombettes 1211 Geneva 20, Switzerland			Yolaine Cussac		
Facsin	nile No. +41 22 338 82 70		e-mail: pt11@wipo.int		

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

Applicant's or agent's file reference Applicant's or agent's file reference 1322-0435 PCT	From the						REC'D U 5 UCI	2005
HEDMAN & COSTIGAN, P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036 Applicant's or agent's file reference 1322-035 PCT International application No. 2 May 2005 (23.05.2005) 21 May 2004 (21.05.2004) 21 May 2004 (21.05.				PCT	WIPO	Р		
SAVENUE OF THE AMERICAS NEW YORK, NY 10036 NE				•				
Applicant's or agent's file reference 1322-035 PCT International application No. International filing date (day/month/year) Priority date (day/month/year) Priority date (day/month/year) 23 May 2005 (23.05.2005) International Patent Classification (IPC) or both national classification and IPC PC(T). AGIK 9/44 and US Cl.: 424/467 Applicant 1. This opinion contains indications relating to the following items: Box No. I Basis of the opinion Box No. II Priority Box No. IV Lack of unity of invention Box No. VI Lack of unity of invention Box No. VI Certain documents cited Box No. VI Certain documents cited Box No. VI Certain defects in the international application 2. FURTHER ACTION If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions is, as provided above, considered to be a written opinion of the Ireflex as written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220. Name and mailing address of the ISA/US Mail Supplements Mail Supplements Page 1850 Date of mailing address of the ISA/US Commissione for Patents Page 1850 Date of mailing address of the ISA/US Commissione for Patents Page 1850 Date of mailing address of the ISA/US Commissione for Patents Page 2850 Date of mailing address of the ISA/US Commissione for Patents Page 2850 Date of mailing address of the ISA/US Commissione for Patents Page 2850 Date of mailing address of the ISA/US Commissione for Patents Page 2850 Date of mailing address of the ISA/US Commissione for Patents Page 2850 Date of mailing address of the ISA/US Commissione for Patents Page 2850 Date of mailing address of the ISA/US Commissione for Pat	1185 AVENUE OF THE AMERICAS					•		
Applicant's or agent's file reference International Form ROR FURTHER ACTION See paragraph 2 below						(PCT Rule 43bi	is.1) ·	
Applicant's or agent's file reference FOR FURTHER ACTION Sce paragraph 2 below 1322-035 PCT International application No. International filing date (day/month/year) Priority date (day/month/year) PCT/USOS/18631 23 May 2005 (23.05.2005) 21 May 2004 (21.05.2004) International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 9/44 and US Cl.: 424/467 Applicant SOLAPHARM, INC.						03	OCT 2003	
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International application No.		,				See paragraph 2 0e10	w	
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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703) 305-3230
Form PCT/ISA/237 (cover sheet) (January 2004)

International application No.

PCT/US05/18631

Box No	o. I Basis of this opinion
1. With r was fi	regard to the language, this opinion has been established on the basis of the international application in the language in which it led, unless otherwise indicated under this item.
	This opinion has been established on the basis of a translation from the original language into the following language which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With a invent	regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed tion, this opinion has been established on the basis of:
a.	type of material
	a sequence listing
	table(s) related to the sequence listing
ъ.	format of material
	in written format
	in computer readable form
C.	time of filing/furnishing
	contained in international application as filed.
	filed together with the international application in computer readable form.
	furnished subsequently to this Authority for the purposes of search.
3. 🗌	In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Addi	tional comments:
	·

International application No.
PCT/US05/18631

Box No. IV Lack of unity of invention	
1. In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:	
paid additional fees	
paid additional fees under protest	
not paid additional fees	
2. This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applica	nt to
pay additional fees. 3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is	
complied with	
not complied with for the following reasons:	
See the lack of unity section of the International Search Report(Form PCT/ISA/210)	
•	
,	
	•
And the control of the international applications	
4. Consequently, this opinion has been established in respect of the following parts of the international application:	
all parts.	
the parts relating to claims Nos. 1-26 and 33	

Form PCT/ISA/237 (Box No. IV) (January 2004)

International application No. PCT/US05/18631

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement			
1. Statement			
Novelty (N)	Claims 13,14 and 16-20	YES	
Hovery (14)	Claims 1-3, 4-12, 15, 21-26, 33	NO	
Inventive step (IS)	Claims NONE	YES	
inventive step (12)	Claims <u>1-26, 33</u>	NO	
Industrial applicability (IA)	Claims 1-26, 33	YES	
moustriat applicationity (123)	Claims NONE	NO	

2. Citations and explanations:

Claims 1-3, 4-12, 15, 21-26, and 33 lack novelty under PCT Article 33(2) as being anticipated by Shah et al. Shah discloses a segmented tablet with two or more segments. The tablet may be broken into pieces and then administered.

Claims 23-25 lack novelty under PCT Article 33(2) as being anticipated by Urban et al. Urban discloses a device for breaking tablets. Said device is disclosed to be useful for breaking tablets in order to allow a subject to administer a reduced dose of the tablet.

Claims 13-14 and 16 lack an inventive step under PCT Article 33(3) as being obvious over Shah, above in view of Hallerback. Shah does not teach the joining of a multitude of segments into a single tablet wherein there are different dosages in each segment. Hallerback teaches a device that contains a multitude of birth control pills, each pill being a tablet that has a different dosage of medicament. Thus, it is obvious to make the plurality of tablets in Hallerback integral by combining them into one tablet as taught by Shah. Making integral is usually a sufficient reason to combine prior art teachings so that such combination need not be suggested by the art itself.

Claims 17 and 18 lack an inventive step under PCT Article 33(3) as being obvious over Shah in view of Addicks. Shah teaches a segmented tablet, but does not teach such a tablet wherein the tablet comprises warfarin. Addicks teaches tablets that comprise warfarin. Thus, it would be obvious to add warfarin to the tablet of Shah in order to obtain a dosage form for warfarin that has the advantages of Shah's tablet.

Claims 17 and 19 lack an inventive step under PCT Article 33(3) as being obvious over Shah in view of Eberlein. Shah teaches a segmented tablet, but does not teach such a tablet wherein the tablet comprises digoxin. Eberlein teaches tablets that comprise digoxin. Thus, it would be obvious to add digoxin to the tablet of Shah in order to obtain a dosage form for digoxin that has the advantages of Shah's tablet.

Claim17 and 20 lack an inventive step under PCT Article 33(3) as being obvious over Shah in view of Franz. . Shah teaches a segmented tablet, but does not teach such a tablet wherein the tablet comprises levothroxine. Franz teaches tablets that comprise levothroxine. Thus, it would be obvious to add levothroxine to the tablet of Shah in order to obtain a dosage form for levothroxine that has the advantages of Shah's tablet.

Claim1-26, and 33 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

To: JAMES V. COSTIGAN HEDMAN & COSTIGAN, P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036 Applicant's or agent's file reference 1322-035 PCT International application No. PCT/US05/18631 23 May 2005 (23.05.2005) International Patent Classification (IPC) or both national classification and IPC WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHO (PCT Rule 43bis.1) PCT/US05/18631 23 May 2005 (23.05.2005) 21 May 2004 (21.05.2004)	
HEDMAN & COSTIGAN, P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036 WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHO (PCT Rule 43bis.1) Date of mailing (day/month/year) Applicant's or agent's file reference 1322-035 PCT International application No. PCT/US05/18631 23 May 2005 (23.05.2005) International Patent Classification (IPC) or both national classification and IPC	
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IPC(7): A61K 9/44 and US C1.: 424/467	
Applicant	
SOLAPHARM, INC.	
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Box No. IV Lack of unity of invention	
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3. For further details, see notes to Form PCT/ISA/220.	

Name and mailing address of the ISA/US

Mail Stop PCT, Athr. ISA/US

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 223 13-1450

Facsimile No. (703) 305-3230

Form PCT/ISA/237 (cover sheet) (January 2004)

Authorized officer

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International application No.

PCT/US05/18631

Box No. 1 Basis of this opinion
1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it
was filed, unless otherwise indicated under this item.
This opinion has been established on the basis of a translation from the original language into the following language which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
a. type of material
a sequence listing
table(s) related to the sequence listing
b. format of material
in written format
in computer readable form
c. time of filing/furnishing
contained in international application as filed.
filed together with the international application in computer readable form.
furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or firmished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:
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Box No. IV Lack of unity of invention
1. In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
paid additional fees
paid additional fees under protest
not paid additional fees
2. This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to
pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
complied with
not complied with for the following reasons:
See the lack of unity section of the International Search Report(Form PCT/ISA/210)
4. Consequently, this opinion has been established in respect of the following parts of the international application:
all parts.
the parts relating to claims Nos. 1-26 and 33

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 13,14 and 16-20 Claims 1-3, 4-12, 15, 21-26, 33	YES NO
Inventive step (IS)	Claims NONE Claims 1-26, 33	YES
Industrial applicability (IA)	Claims 1-26, 33 Claims NONE	YES NO

2. Citations and explanations:

Claims 1-3, 4-12, 15, 21-26, and 33 lack novelty under PCT Article 33(2) as being anticipated by Shah et al. Shah discloses a segmented tablet with two or more segments. The tablet may be broken into pieces and then administered.

Claims 23-25 lack novelty under PCT Article 33(2) as being anticipated by Urban et al. Urban discloses a device for breaking tablets. Said device is disclosed to be useful for breaking tablets in order to allow a subject to administer a reduced dose of the tablet.

Claims 13-14 and 16 lack an inventive step under PCT Article 33(3) as being obvious over Shah, above in view of Hallerback. Shah does not teach the joining of a multitude of segments into a single tablet wherein there are different dosages in each segment. Hallerback teaches a device that contains a multitude of birth control pills, each pill being a tablet that has a different dosage of medicament. Thus, it is obvious to make the plurality of tablets in Hallerback integral by combining them into one tablet as taught by Shah. Making integral is usually a sufficient reason to combine prior art teachings so that such combination need not be suggested by the art itself.

Claims 17 and 18 lack an inventive step under PCT Article 33(3) as being obvious over Shah in view of Addicks. Shah teaches a segmented tablet, but does not teach such a tablet wherein the tablet comprises warfarin. Addicks teaches tablets that comprise warfarin. Thus, it would be obvious to add warfarin to the tablet of Shah in order to obtain a dosage form for warfarin that has the advantages of Shah's tablet.

Claims 17 and 19 lack an inventive step under PCT Article 33(3) as being obvious over Shah in view of Eberlein. Shah teaches a segmented tablet, but does not teach such a tablet wherein the tablet comprises digoxin. Eberlein teaches tablets that comprise digoxin. Thus, it would be obvious to add digoxin to the tablet of Shah in order to obtain a dosage form for digoxin that has the advantages of Shah's tablet.

Claim17 and 20 lack an inventive step under PCT Article 33(3) as being obvious over Shah in view of Franz. Shah teaches a segmented tablet, but does not teach such a tablet wherein the tablet comprises levothroxine. Franz teaches tablets that comprise levothroxine. Thus, it would be obvious to add levothroxine to the tablet of Shah in order to obtain a dosage form for levothroxine that has the advantages of Shah's tablet.

Claim1-26, and 33 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.